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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Makoto Noami

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EXAMINER

BUIE-HATCHER, NICOLE M

ART UNIT

PAPER NUMBER

1796

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,739	Applicant(s) NOAMI ET AL.	
	Examiner NICOLE M. BUIE-HATCHER	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 14-16 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) 23-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14-16, 21 and 22 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☒ Claim(s) 12, 14-16 and 21-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20091203</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/14/2009 has been entered.

Response to Amendment

The amendment filed 12/14/2009 has been entered. Claims 12 and 14-16 remain pending. Claims 21-27 have been added. The previous 112, second paragraph, rejection of claims 11 and 12 are withdrawn in light of Applicants' cancellation of claim 11 and amendment of claim 12.

Election/Restrictions

Newly submitted claims 23-27 directed to an invention that lacks unity with the invention originally claimed for the following reasons:

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Art Unit: 1796

Group I, claim(s) 1-22, drawn to composition.

Group II, claim(s) 23-26, drawn to a process of coating.

Group III, claim(s) 27, drawn to process of binding.

The inventions listed as Groups I, II, and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: while a resin composition obtained by copolymerizing a polyvinyl alcohol having an average polymerization degree of 1300 or less and at least one or more polymerizable vinyl monomer(s) in a weight ratio of 6:4 to 9:1 is shared between all three groups, it doesn't offer contribution over the prior art, because said resin composition is disclosed in Hoshi et al. (US 2003/0166763, Synthesis Examples 1-3).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, **claims 23-27 are withdrawn** from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claim 14 in which claim 12 depends, there is more methyl

Art Unit: 1796

methacrylate than acrylic acid. However, in claim 12, the acrylic acid may be more the methyl methacrylate.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 14, 21, and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Hoshi et al. (US 2003/0166763).

Regarding claims 14, 21, and 22, Hoshi et al. discloses in Synthesis Example 2 and Table 2, PVA-SH (degree of polymerization of 500 and 1500 mixed together, both degree of hydrolysis 88%) wherein the amounts of PVA-SH of degree of polymerization is 50% of 75 parts. Therefore the ratio PVA-SH of degree of polymerization of 500 to the rest of the monomers is 1.5 which meets the endpoint. In E-2002 the amount of acrylic acid and methyl methacrylate is “0.25” which is within the claimed range. In Synthesis Example 4 and Table 4, PVA (degree of polymerization 500 and 1700, both degree of hydrolysis 88%) wherein the amounts of PVA-SH of degree of polymerization is 50% of 75 parts. Therefore the ratio PVA-SH of degree of polymerization of 500 to the rest of the monomers is 1.5 which meets the endpoint. In E-4002, the amount of acrylic acid to methyl methacrylate is 0.25 which is within the claimed ratio. In both examples, ion exchange water is present before the films are prepared.

Art Unit: 1796

However, Hoshi et al. does not disclose the aqueous composition is used for coating medicines, animal drugs, agricultural chemicals, fertilizers or foods. The recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). See MPEP § 2111.02.

Claim 16 is rejected under 35 U.S.C. 102(a) as being anticipated by Hoshi et al. (US 2003/0166763).

Regarding claim 16, Hoshi et al. discloses in Synthesis Example 2 and Table 2, PVA-SH (degree of polymerization of 500 and 1500 mixed together, both degree of hydrolysis 88%) wherein the amounts of PVA-SH of degree of polymerization is 50% of 75 parts. Therefore the ratio PVA-SH of degree of polymerization of 500 to the rest of the monomers is 1.5 which meets the endpoint. In E-2002 the amount of acrylic acid and methyl methacrylate is “0.25” which is within the claimed range. In Synthesis Example 4 and Table 4, PVA (degree of polymerization 500 and 1700, both degree of hydrolysis 88%) wherein the amounts of PVA-SH of degree of polymerization is 50% of 75 parts. Therefore the ratio PVA-SH of degree of polymerization of 500 to the rest of the monomers is 1.5 which meets the endpoint. In E-4002, the amount of acrylic acid to methyl methacrylate is 0.25 which is within the claimed ratio. In both examples, ion exchange water is present before the films are prepared.

However, Hoshi et al. does not disclose a binder for a medicine, an animal drug, an agricultural chemical, a fertilizer, or a food. The recitation of a new intended use for an old

Art Unit: 1796

product does not make a claim to that old product patentable. *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). See MPEP § 2111.02.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 14, 15, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Angel et al. (US 2002/0042466). *This is an alternative rejection of claim(s) 12, 14, 21, and 22 above to meet an earlier priority date.*

Regarding claims 12, 14, 15, 21, and 22, Angel et al. discloses water-soluble or water-dispersible copolymers used as a coating agent, binder comprising monomers including methyl methacrylate which is particularly preferred [0028] wherein the amount may be the same as the

Art Unit: 1796

hydroxyl alkyl (meth)acrylate [0041] and the amount of both of these monomers is from 80 to 20% [0019]. Acrylic acid is a preferred compound for (c) which is present from 0 to 20% by weight [0025]. The polyvinyl alcohol (PVA) is present from 20 to 80% by weight [0024]. PVA may be partially hydrolyzed as well as completely hydrolyzed having a degree of hydrolysis from preferably from 65 to 99% which is within the claimed range [0039]. The molecular weight of PVA is particularly 10,000 to 100,000 (Based on calculations, the degree of polymerization is from 227 to 2270 based on the degree of polymerization is equal to the molecular weight of the polymer divided by the molecular weight of the repeating unit which is 44.05). Angel et al. discloses the coating may be used for tablets, coating other pharmaceutical preparations [0080-0081]. The polymers are prepared in water [0054] which the dispersion or solution is used for the coating [0064].

It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges of PVA, acrylic acid, methyl methacrylate, and degree of polymerization disclosed by the reference because overlapping ranges have been held to be a prima facie case of obvious. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Angel et al. (US 2002/0042466). *This is an alternative rejection of claim(s) 16 above to meet an earlier priority date.*

Regarding claim 16, Angel et al. discloses water-soluble or water-dispersible copolymers used as a coating agent, binder comprising monomers including methyl methacrylate

Art Unit: 1796

which is particularly preferred [0028] wherein the amount may be the same as the hydroxyl alkyl (meth)acrylate [0041] and the amount of both of these monomers is from 80 to 20% [0019].

Acrylic acid is a preferred compound for (c) which is present from 0 to 20% by weight [0025].

The polyvinyl alcohol (PVA) is present from 20 to 80% by weight [0024]. PVA may be partially hydrolyzed as well as completely hydrolyzed [0039].]. The molecular weight of PVA is particularly 10,000 to 100,000 (Based on calculations, the degree of polymerization is from 227 to 2270 based on the degree of polymerization is equal to the molecular weight of the polymer divided by the molecular weight of the repeating unit which is 44.05). Angel et al. discloses the coating may be used for binders [0089]. The polymers are prepared in water [0054] which the dispersion or solution is used [0065-0066].

It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges of PVA, acrylic acid, methyl methacrylate, and degree of polymerization disclosed by the reference because overlapping ranges have been held to be a prima facie case of obvious. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05.

Response to Arguments

Applicant's arguments filed 12/14/2009 have been fully considered and are substantially persuasive. The following comments apply:

A) Since the polymerization degree disclosed in JP 20020105383 A overlaps one point, the previous rejection over this reference has been withdrawn.

Art Unit: 1796

B) Applicants' argument that Hoshi et al. describes a hard capsule and not a composition for coating medicines, animal drugs, agricultural chemicals, fertilizers or foods (page 6) is not persuasive. The recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). See MPEP § 2111.02.

C) Applicants' argument that Hoshi et al. do not teach a PVA having "an average polymerization degree of 300 to 500", but rather a mixture of two PVAs having an average polymerization degree of 500 and 700 (page 6) is not persuasive. The composition of claim 14 has the transitional phrase "comprising" is open-ended and does not exclude additional, unrecited elements. See MPEP § 2111.03. The PVA having a degree of polymerization of 700 is just an additional component.

D) Applicants' argument that PVA-SH is structurally different from the PVA-OH that is used in the present invention (page 7) is not persuasive. Since PVA-SH contains vinyl alcohol repeating units, the PVA-SH of Hoshi et al. still meets the claimed limitations.

E) Applicants' argument that Hoshi et al. do not teach or suggest a process of coating medicines, animal drugs, agricultural chemicals, fertilizers or foods as recited in claim 23 (page 7) is not persuasive. Claim 23 has not been treated on the merits based on election by original presentation; therefore Applicants' arguments are not germane.

F) Saliba has been withdrawn from the previous rejection as an evidentiary reference, since this reference was not needed for the above composition claims.

Art Unit: 1796

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE M. BUIE-HATCHER whose telephone number is (571)270-3879. The examiner can normally be reached on Monday-Thursday with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571)272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/
Supervisory Patent Examiner, Art Unit 1796

/N. M. B./
Examiner, Art Unit 1796
12/24/2009